Medical Devices Update

Medical devices industry cautiously optimistic

Plastics firms continue prominent role in development, production

To a large degree, the medical devices industry runs on plastics. So ubiquitous are plastics in medical technology that Massachusetts-based BCC Research recently conducted a study limited to plastics usage in medical devices with sustained average annual growth rates "far in excess of the Gross Domestic Product." In summarizing the study need BCC officials noted, "The aging of the U.S. population, continuing cost reduction pressures in the healthcare field, advances in polymer performance, introduction of new and often life-saving devices, and the ever-present environmental/disposable/nondisposable medical device triad warrant an in-depth study as we continue into this decade." The study is available for a cost on BCC's Website.

The medical device industry is in fact a strong driver of the U.S. economy, according to a June 2009 study conducted by the Medical Device Manufacturers Association in conjunction with the National Venture Capital Association. Titled *Medical Technology and Venture Capital: A Fruitful but Fragile Ecosystem*, the study reported that the medical devices industry "accounted for 2.7 percent of U.S. GDP in 2006 and is responsible for nearly 2 million jobs – equivalent to 1.4 percent of total U.S. employment."

The joint study noted that the U.S. medical technology industry is the only net exporter of medical devices in the world, generating a $5.4 billion trade surplus. Researchers for the study also sought to refute what they called a "false perception" that medical devices are driving up health care costs. "In point of fact, medical devices continue to account for less than 5 percent of hospital expenditures; spending on medical technology as a share of total health services and supplies expenditures dropped from 5.8 percent in 1980 to 3 percent in 2006. Furthermore, these devices have significantly improved patient care and have reduced the long-term costs of care."

Progress through polymers

With so many specialized products to its credit, it should come as no surprise that the medical devices industry is supported by manufacturers boasting expertise in specialized technical processes. Russell Johnson, President of China Array Plastics, noted in a recent article that "high performance thermoplastic (HPTP) components are a critical part of many medical devices. HPTPs possess unique properties suited to medical applications: resistance to chemicals and repeated autoclaving, dimensional integrity, strength, stiffness and fatigue resistance."

Those desirable properties, explained Johnson, reside within the polymers and, "It is the molder's mission to transfer those inherent properties into the finished goods." It's not an easy task since "HPTPs require a much higher degree of specialized engineering than conventional

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plastics." Creating the correct compound for an HPTP application is a sophisticated science. Molding HPTPs, which have higher melt temperatures than conventional plastics (400°C vs. 150°C), as well as different viscosities and flow characteristics, places unique demands on product design, mold-making and the injection molding process. Not surprisingly, "Most medical device companies do not have in-house HPTP application engineers, choosing instead to work with consultants on a project-by-project basis."

Associated Polymer Labs in New York advises that plastic part compatibility and material selection can be just as important as shelf life stability, product performance and FDA compliance. APL supports new product feasibility studies by testing materials for compatibility. At all stages of the product development process, "Integrity is absolutely paramount for medical device companies," says David Witt, a researcher with Illinois-based PCC (Plastics Color Corporation). "Medical device manufacturers have to be certain that for each product produced, every component and every process involved adhere to compliance standards."

To meet the additive masterbatch and plastics color demands of the medical devices industry, PCC opened its 7,000 square foot *Plant Within a Plant* in 2008. This closed-loop production facility was designed with input from medical experts who cited reducing contamination risk as a paramount concern. "It has been important for customers to see how we handled materials and how the cross-contamination risk has been almost eliminated by using such equipment as a sterilized water bath utilizing UV filtration and a closed-loop water system," explains Joe Byrne, PCC's vice president for sales and marketing.

PCC President Douglas Borgsdorf adds that the *Plant Within a Plant* anticipates the industry's general requirements for 2014: optimal production turnarounds and a closed-loop manufacturing system — a resource-planning architecture in which production planning drives the master schedule that in turn drives the material plan that dictates the capacity plan.

In fact, demand is increasing so quickly that in May, PCC announced plans to open a new facility in California that is based on the success of its Plant Within a Plant clean compounding facility. The plant will open this fall with two segregated clean lines targeted squarely at the medical, pharmaceutical and food packaging industries.

Optimism amid uncertainty

It may take several years for the U.S. government to iron out and effectuate all of the details of recently-adopted national health care legislation. But Mark Leahey, president and CEO of the Medical Device Manufacturers Association (MDMA), said his organization's members are already "very concerned about the impact that a $20 billion device tax will have on patient care." In a March 25, 2010 article in *Plastics News*, Leahey also noted that "If eliminating the tax is not possible, structuring it to provide relief for smaller companies is critical. Under the current structure, many companies will owe more in taxes than they generate in profits, requiring companies to lay off employees, cut R&D budgets and slow the development of new therapies that will improve the quality of care for all Americans."

While the prospect of additional taxation and scrutiny looms large, the medical devices industry maintains its share of optimists about the future.

"For the second consecutive quarter, medical device manufacturers remain optimistic about prospects for sales and employment growth in the coming year. Despite the passage of a new and burdensome federal excise tax on medical devices, companies are continuing to design innovative medical products and meet the unmet needs of the health care delivery system worldwide," said Tom Sommer, president of MassMEDIC in a statement accompanying a March, 2010 survey. (MassMEDIC is the Massachusetts state association of medical device companies.)

Nearly three out of five companies surveyed said they expected an uptick in business by early summer, while less than five percent of medical device businesses surveyed said they expected things to worsen. In addition, nine out of 10 businesses surveyed said they expected headcount to remain the same or increase by early summer 2010.

The end of the first calendar quarter of 2010 wasn't solely about landmark healthcare legislation in the U.S. On March 21, amendments to the EU Medical Device Directive (MDD) went into effect. Directive 2007/47/EC represented the first significant changes to the MDD in over 15 years. For medical device firms in the U.S. doing business or seeking to do business in the EU, the changes might prompt a review of current practices to stay up to date with requirements for the CE Mark. (A **CE Mark** demonstrates a product's compliance with relevant European legislation.)

Among the new MDD changes are more stringent requirements for clinical data and post-market monitoring of device usage, and changes to the definition of a "medical device." For the first time, software used for diagnostic purposes is now considered a medical device in the EU market.

Any medical device with a classification modified by the latest changes (2007/47/EC) will need a new certification if it is placed on the market or put into service after March 21 2010.

For more information on clean room technology, color and masterbatch additives for the medical devices industry, contact Joe Byrne of PCC at 800-922-9936 or visit www.plasticscolor.com.